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EXAMINER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LLOYD H. MALCHOW, PAUL LUBOCK,
and DEREK DAW

Appeal 2015-005241
Application 11/980,308
Technology Center 3700

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

PER CURIAM

DECISION ON APPEAL

This is an appeal¹ under 35 U.S.C. § 134 involving claims to a biopsy system with integrated imaging and a method of taking a biopsy specimen. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ Appellants identify the Real Party in Interest as SenoRx, Inc. (*see* App. Br. 3).

Statement of the Case

Background

Appellants' invention relates to "systems and methods for imaging and removing tissue from a location within a patient and particularly to a biopsy system which has an integrated imaging system" (Spec. ¶ 2).

The Claims

Claims 1 and 45–58 are on appeal. Independent claim 1 is representative and reads as follows (emphasis added):

1. A biopsy system, comprising:
 - a. a main computer module;
 - b. a tissue removal system which includes a tissue removal control module, and a vacuum module having a valve, the tissue removal control module being connected by a wired connection to the main computer module to communicate with the main computer module, the tissue removal control module configured to connect to a tissue removal probe, and the tissue removal control module being connected in communication with the valve of the vacuum module;
 - c. an ultrasonic imaging system configured to communicate with an ultrasonic imaging probe, the ultrasonic imaging system having an interface connected by a wired connection to the main computer module to communicate with the main computer module;
 - d. an image display screen connected by a wired connection to the main computer module to communicate with the main computer module, the image display screen being configured to display an ultrasonic image based upon data received from an ultrasound probe data and processed by the main computer module; and
 - e. an input console having at least one of a keyboard and a touch-screen display, *the input console being connected by a wired connection to the main computer module to communicate with the main computer module, the input console being*

communicatively coupled to each of the tissue removal control module and the ultrasonic imaging system via the main computer module, the input console being configured to provide control information for the ultrasonic imaging system and the input console being configured to provide control information for the tissue removal control module of the tissue removal system.

*The Issue*²

The Examiner rejected claims 1 and 45–58 under 35 U.S.C. § 103(a) as obvious over Burdorff³ and Steins⁴ (Ans. 6–14).

The Examiner finds that Burdorff teaches a biopsy system having

- a. a **main computer module** mounted on a moveable cart (*i.e. controllable device and console, Paragraphs 32–35 and Figure 3 depicting the inclusion of the computer module on a cart with wheels*);
- b. a **tissue removal system** which includes a **tissue removal control module** (*i.e. the tissue removal control module corresponds to a “microprocessor-based electrical device”. . . ; Burdorff teaches “a first and a second controller and driver, 390 and 406, convert digital signals from microprocessor 408 into analog motor signals for controlling power transmission source 24 rotational direction and speed” for the biopsy tissue removal system, see Paragraph 39 as well as other locations of the specification describing control functionality associated with the microprocessor*), and a **vacuum control module having a valve** (*i.e. under the broadest reasonable interpretation a “valve” is understood to be a device that regulates or controls the flow of a fluid or gas; Burdorff teaches that the lateral vacuum lines are opened and closed automatically by the system to control the flow of the fluid to the fluid canister 318 (see Paragraph 53)), the tissue*

² The rejection of claims 1 and 45–58 under 35 U.S.C. § 112, first paragraph, has been withdrawn (*see* Ans. 14).

³ Burdorff et al., US 2004/0210161 A1, published Oct. 21, 2004.

⁴ Steins et al., US 6,733,458 B1, issued May 11, 2004.

removal control module being connected by a wired connection to the main computer module to communicate with the main computer module (*Paragraph 31; also note Figure 4 showing the connectivity between system components*), the tissue removal control module configured to connect to a tissue removal probe (*see Figure 1, depicting that both the “control unit 300” and the “remote control device 16” are functionally and materially connected to the tissue removal probe*), and the tissue removal control module being connected in communication with the valve of the vacuum control module (*see Figure 1, depicting that the “control unit 300[”] and the “remote control device” are functionally and materially connected to the “fluid collection system 22” which comprises the aforementioned vacuum lines that control flow*);

c. an **image display screen** connected by a wired connection to the main computer module to communicate with the main computer module (*i.e. “Video monitor 28 displays the image shown on a display 334 mounted on console 302”, see Paragraph 33 and Figure 3*); and

d. an **input console** having at least one of a keyboard and a touch-screen display (*i.e. “touchscreen 336”, see Paragraph 37*), the input console being connected by a wired connection to the main computer module to be in communication with the main computer module, the input console being communicatively coupled to the tissue removal control module via the main computer module, the input console being configured to provide control information for the tissue removal control module of the tissue removal system (*i.e. controlling the probe and surgical biopsy system, see Paragraphs 32, 34 and 35*).

(Ans. 8–10.) The Examiner finds that Burdorff teaches that

“[a]n operator may use surgical biopsy system 10 with a handheld, ultrasonic imaging device for visualizing the removal of suspected tissue from a patient. The imaging device provides a real-time image of lesions, microcalcifications, and high-density masses within the breast tissue of the patient. The operator may view a suspected tissue mass while guiding

piercer tip 72 of handpiece 40 to a location adjacent to the suspected tissue in order to obtain a core tissue sample. The surgical biopsy system 10 may also be mounted in a holder of a mechanical arm or the like, and used with other imaging devices such as stereotactic X-ray” (see Paragraph 30).

(*Id.* at 10.)

The Examiner acknowledges that “Burdorff does not expressly disclose an integrated **ultrasonic imaging system** configured to communicate with an ultrasonic imaging probe, the ultrasonic imaging system having an interface connected by a wired connection to the same main computer module responsible for operating the biopsy/tissue removal system” (*id.*).

The Examiner turns to Steins and finds that it teaches a diagnostic medical ultrasound system and method using image based freehand needle guidance, which specifically teaches **the ultrasonic imaging probe and biopsy system being integrated and controlled by a main system controller** and a main user interface (*see Figure 1 and Column 5, Lines 1–43*). This teaching of an integrated controller responsible for **both** tissue removal functions and ultrasound imaging functions is shown in Steins’ Figure 1. . . . Note that the “system controller” can both receive information from, and send control information to, the “location (position and/or orientation) calculator 126” (i.e. the tissue removal control module) as well as the ultrasound components within boxes 108, 110 and the probe and sensor components (i.e. the ultrasonic imaging probe).

(*Id.* at 11.)

The Examiner concludes that it would have been obvious to “combine the teachings of Burdorff and Steins because both inventions are directed to ultrasonically imaged biopsy systems and Burdorff specifically acknowledges the usefulness of an ultrasonic imaging system in conjunction

with the biopsy system for improving the accuracy of the tissue removal procedure (*Burdorff: Paragraphs 30 and 34*)” (*id.* at 12).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Burdorff and Steins render the claims *prima facie* obvious?

Findings of Fact

1. Burdorff teaches that

[a] surgical biopsy system is provided for removing at least one tissue sample from a surgical patient. The surgical biopsy system comprises an elongated, hollow piercer and a cutter rotatably and axially positionable relative to the piercer.

. . . The surgical biopsy system further comprises a power transmission source operatively connected to the cutter for rotating and translating the cutter, a control unit, and a display mounted in a display frame for showing an operator a plurality of operational modes of the surgical biopsy system.

(Burdorff Abstract; *see also* Ans. 6.)

2. Figure 4 of Burdorff is reproduced below:

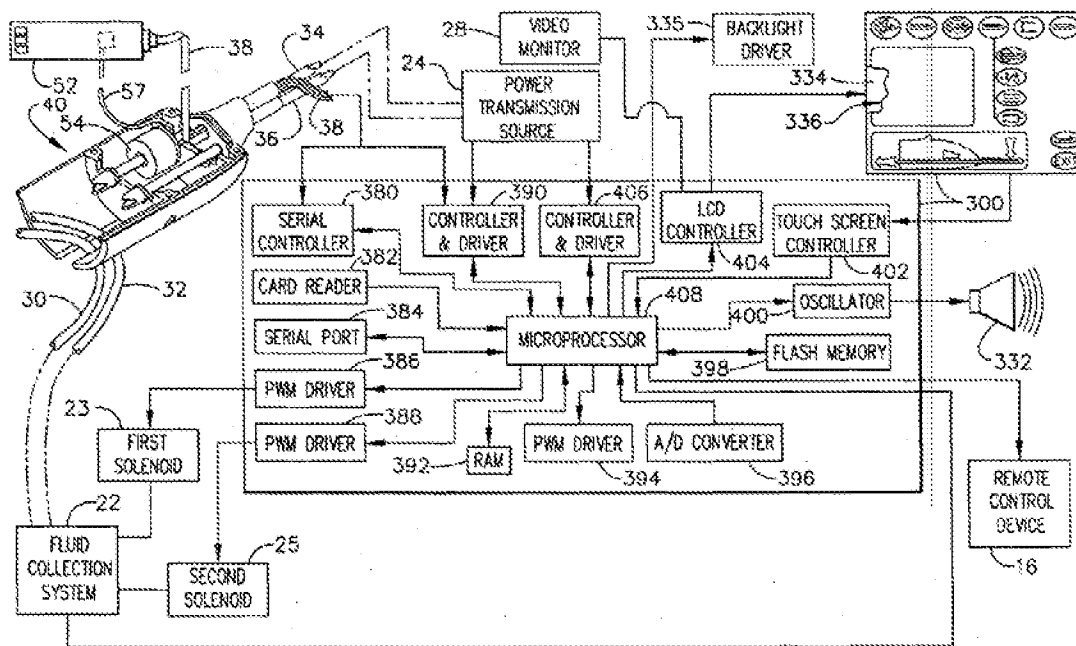


FIG. 4

Figure 4 shows

a first and a second controller and driver, **390** and **406**, convert digital signals from microprocessor **408** into analog motor signals for controlling power transmission source **24** rotational direction and speed. Closed loop, digital, translation speed control of power transmission source **24** is also achieved within controller and driver **390** using feedback signals from rotation sensor **54** in handpiece **40**. Handpiece **40** contains a switchboard **52** having a first circuit **212**. . . . A serial controller **380** is electronically connected to switchboard **52** by control cord **38**. Serial controller **380** coordinates information exchange across the serial communication link between switchboard **52** and microprocessor **408**.

(Burdorff ¶ 39; *see also* Ans. 7–10.)

3. Burdorff teaches that “[a]n operator may use surgical biopsy system **10** with a handheld, ultrasonic imaging device for visualizing the

removal of suspected tissue from a patient” (Burdorff ¶ 30; *see also* Ans. 10).

4. Steins teaches

A diagnostic medical ultrasound system having an integrated invasive medical device guidance system is disclosed. The guidance system obtains image slice geometry and other imaging parameters from the ultrasound system to optimize the guidance computations and visual representations of the invasive medical device and the imaged portion of the subject. Further, the ultrasound system obtains guidance data indicating the relative location, i.e. position and/or orientation of the invasive medical device relative to the transducer and imaging plane to optimize the imaging plane and ultrasound beam characteristics to automatically optimally image both the imaged portion of the subject and the invasive medical device.

(Steins Abstract; *see also* Ans. 11.)

5. Figure 1 of Steins is reproduced below:

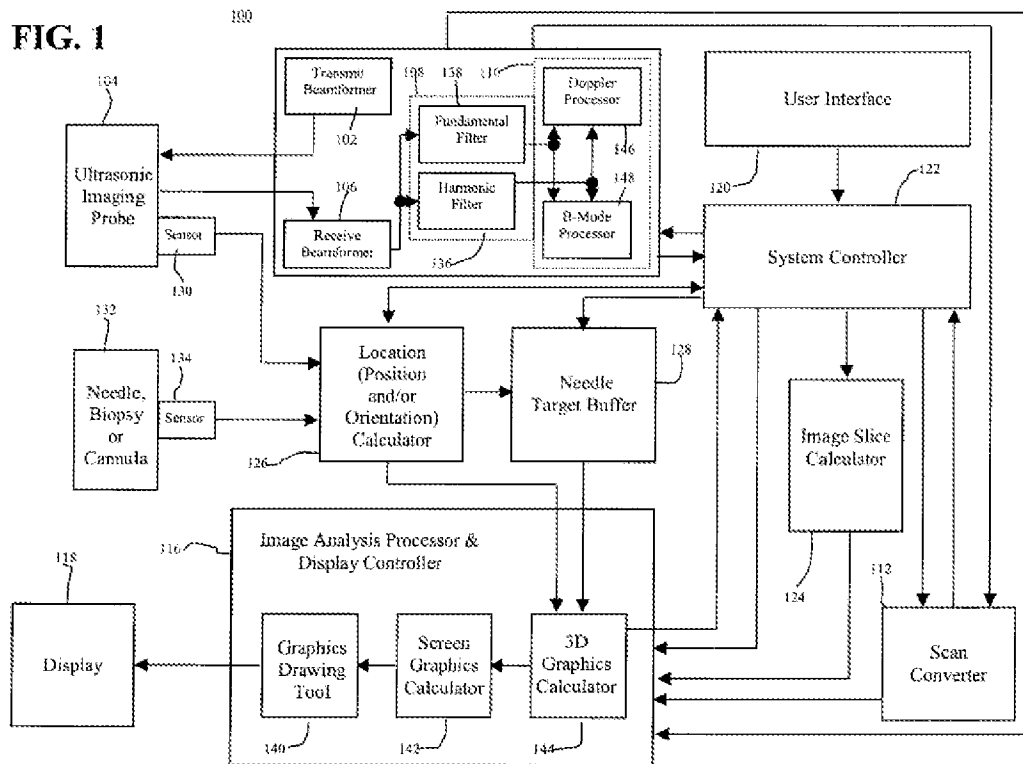


Figure 1 shows that [t]he ultrasound system **100** . . . includes a transmit beamformer **102**, an ultrasonic imaging probe or transducer **104**, a receive beamformer **106**, a filter block **108**, a signal processor **110**, a scan converter **112**, an image data storage **114**, an image processor **116** and a display **118**” (Steins 5:25–29; *see also* Ans. 11).

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417.

Analysis

We adopt the Examiner’s findings of fact and reasoning regarding the scope and content of the prior art (Ans. 2–19; FF 1–5) and agree that the claims are obvious over Burdorff and Steins. We address Appellants’ arguments below.

Claim 1

Appellants contend that

nothing [in Burdorff] discloses or suggests an input console being communicatively coupled to each of the tissue removal control module **and** the ultrasound imaging system via the main computer module, as required in claim 1. More particularly . . . , nothing in the cited passages from Burdorff discloses or suggests “the **input console being communicatively coupled** to each of the **tissue removal control module and the ultrasonic imaging system** via the main computer module, the **input console being configured to provide control information for the ultrasonic imaging system** and the **input console being configured to provide control information for the tissue removal control module of the tissue removal system**”, as recited in claim 1. (Emphasis added).

(App. Br. 24; *see also id.* at 25–26; *see also* Reply Br. 10–11.)

This argument is unpersuasive.

Steins teaches

A diagnostic medical ultrasound system having an *integrated* invasive medical device guidance system is disclosed. The guidance system obtains image slice geometry and other imaging parameters from the ultrasound system *to optimize the guidance computations and visual representations of the invasive medical device and the imaged portion of the subject*. Further, the ultrasound system *obtains guidance data indicating the relative location, i.e. position and/or orientation of the invasive medical device relative to the transducer and imaging plane to optimize the imaging plane and ultrasound*

beam characteristics to automatically optimally image both the imaged portion of the subject and the invasive medical device.

(FF 1 (emphasis added).) As the Examiner explains,

applicant is arguing that Burdorff does not disclose that the ultrasonic imaging device is “communicatively coupled” (i.e. functionally linked) to the control unit of the surgical biopsy system, however this is conceded by the examiner. In fact, this is the basis for the combination with Steins (see Rejection under 103 above, noting that “*Burdorff does not expressly disclose an integrated ultrasonic imaging system configured to communicate with an ultrasonic imaging probe, the ultrasonic imaging system having an interface connected by a wired connection to the same main computer module responsible for operating the biopsy/tissue removal system*”).

(Ans. 16; FF 4–5.) Accordingly, Appellants’ contention fails to account for Steins’ contributions to the combination of Burdorff and Steins. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). “Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references []. [The reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole.” *In re Merck & Co.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

Appellants argue that

the Steins diagnostic medical ultrasound system does not include any output from the system to provide any control to the invasive medical device 132 (needle biopsy or cannula). For example, as shown in Steins Fig. 1, there is only unidirectional communication from the sensor 134 to location calculator 126, and as such there is no capability to control

invasive medical device 132 by the system controller 122, nor does Steins disclose any desire to do so.

(App. Br. 27; *see also* Reply Br. 9, 11, 13–15.)

We are not persuaded. As the Examiner explains, applicant’s claim requires only that “the input console being configured to provide control information for the ultrasonic imaging system and the input console being configured to provide control information for the tissue removal control module of the tissue removal system” (see Claim 1). Applicant seems to argue that Steins lacks the feature of providing control information to the probe itself, however this feature is not present in the claims. The only reference to the probe itself is that the “tissue removal control module [is] configured to connect to a tissue removal probe” (see Claim 1, Lines 6–8). In this case, the tissue removal control module is different from the probe. Rather, it is the processor which controls and manages the probe data. . . . Accordingly, the relevant component is the “Location (Position and/or Orientation) Calculator 126”. As can be seen in Figure 1, the “Location (Position and/or Orientation) Calculator 126” is communicatively coupled to nearly every other component within the system. For instance, system controller 122 has both a send and receive relationship with “Location (Position and/or Orientation) Calculator 126,” and the system controller 122 *also* has a send and receive relationship with the ultrasonic components contained in element 108, 110, and by virtue of this connection, the system controller 122 also has a send and receive relationship with the ultrasonic imaging probe 104. Applicant’s claim does not require a *direct* wired connection; it simply requires that the components be configured to communicate.

(Ans. 17; *see also id.* at 18; FF 5.) *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993). *See also In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) (“[A]ppellant’s arguments fail from the outset because ... they are not based on limitations appearing in the claims.”). Moreover, we observe that

Burdorff teaches “a first and a second controller and driver, **390** and **406**, convert digital signals from microprocessor **408** into analog motor signals for controlling power transmission source **24** rotational direction and speed” (FF 2).

Appellants argue that

[c]onsidered together, both Burdorff and Steins disclose systems having an imaging system that is communicatively separate from the biopsy (medical) device. As such, in both references, there is no attempt to provide an input console or joint computer control of both the imaging system and the biopsy (medical) device, or any reference to a desire to do so, or any teaching of how such might be achieved.

(App. Br. 27.)

We are not persuaded. As the Examiner explains, the system of Steins discloses that the input console (i.e. user interface) is linked to control (via the system controller 122) both the imaging components (see 110 and 108 and other ultrasound components such as 104, 102 and 106) and the biopsy components (i.e. the needle target buffer 128 and the Location (Position and/or Orientation) Calculator 126).

(Ans. 19; FF 5.)

Appellants contend that

to achieve the invention as recited in claim 1 by the combination of Burdorff and Steins (if at all), significant change in the structure and function of the combined elements of Burdorff and Steins would have been required. Thus, for reasons set forth above, the improved structure provided by the present invention over that of Burdorff in view of Steins is more than the predictable use of the elements of Burdorff in view of Steins according to their established functions.

(App. Br. 29.)

We find Appellants' arguments, lacking supporting evidence, insufficient to rebut the express teaching of Burdorff and Steins. *See In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (“[A]ttorney argument [is] not the kind of factual evidence that is required to rebut a prima facie case of obviousness”). Appellants fail to establish an evidentiary basis on this record to support a conclusion that the combination is not simply “the predictable use of prior art elements according to their established functions.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

Claim 54

In regard to claim 54, Appellants contend that

the full claim term is “simultaneously communicatively coupled”, and not just the “communicatively coupled” as in this part of the Office’s argument. . . . in Burdorff, the handheld ultrasound imaging device is distinct and separate from the biopsy system, and thus only in hindsight and with the benefit of Appellant’s disclosure would one of ordinary skill in the art conclude a communication between the biopsy system and the handheld ultrasound imaging device.

(App. Br. 30; *see also id.* at 31–33.)

We do not find this argument persuasive. As the Examiner explains, “the term ‘simultaneously communicatively coupled’ is taught by Steins’ Figure 1 disclosure, in which the system controller is “simultaneously” configured to provide control functionality to the ultrasound components as well as the tissue removal components” (Ans. 19; FF 4–5). *See In re Merck & Co.*, 800 F.2d at 1097.

We have considered, but find unpersuasive, Appellants’ contention that “since the term ‘tissue removal control module’ is defined in the specification in terms of structure, it is respectfully submitted that the term

‘tissue removal control module’ does not invoke interpretation in the claims under 35 U.S.C. 112, sixth paragraph” (Reply Br. 7).

“‘Module’ is a well-known nonce word that can operate as a substitute for ‘means’ in the context of § 112, para. 6. As the district court found, “‘module’ is simply a generic description for software or hardware that performs a specified function.”” *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015). The portion of the Specification identified by Appellants at paragraph 27 does not provide sufficiently definite structure to take the claim limitation out of the ambit of § 112, para. 6 because the only structure required by paragraph 27 is a “microprocessor-based electrical device with built-in software”. The specific functions performed by this component are generically recited as software without any specific requirements.

Claims 45, 55, 56

In regard to claims 45 and 55, Appellants rely on the arguments presented for claim 1 (*see* App. Br. 34, 36). We thus, are not persuaded for the reasons discussed above.

Claims 46 and 47

Appellants contend that

nowhere in Burdorff in view of Steins is there any disclosure or suggestion of a system having a main computer module (common to both of the tissue removal system and the ultrasonic imaging system) that communicates through a first communication link with the tissue removal control module and through a second communication link with the ultrasonic imaging system to **interchange data** therebetween, as recited in claim 46.

(App. Br. 35.)

This argument is similar to Appellants' arguments above in regard to claim 1 concerning having a tissue removal control module and an ultrasonic imaging system (*see id.* at 24), and contending that Stein does not control the invasive medical device (*see id.* at 27). Accordingly, we are not persuaded for the reasons discussed above.

Claims 48–53

In regard to claims 48–53, Appellants rely on the arguments presented for claim 45 (*see id.* at 36). We thus, are not persuaded for the reasons discussed above.

Claims 57 and 58

In regard to claim 57, Appellants rely on the arguments presented for claim 54, and in regard to claim 58, Appellants rely on the arguments presented for claim 56 (*see id.* at 37). We thus, are not persuaded for the reasons discussed above.

SUMMARY

In summary, we affirm the rejection of claims 1 and 45–58 under 35 U.S.C. § 103(a) as obvious over Burdorff and Steins.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED